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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,976	09/15/2006	David I. Cohen	51311-00001	2807
45200	7590	09/09/2008		
K&L Gates LLP 1900 MAIN STREET, SUITE 600 IRVINE, CA 92614-7319				
EXAMINER				
PARKIN, JEFFREY S				
ART UNIT		PAPER NUMBER		
1648				
MAIL DATE		DELIVERY MODE		
09/09/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/598,976

Applicant(s)

COHEN, DAVID I.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 2, 4, 6 and 10-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5, 8 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September, 2006, is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the communication filed 19 June, 2008. Applicant's election of Group II (claims 1, 3, 5, 8, and 9) is noted. Because applicant did not distinctly and specifically point out the purported errors in the restriction requirement, the election has been treated as an election without traverse (refer to M.P.E.P. § 818.03(a)). Claims 2, 4, 6, and 10-16 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

35 U.S.C. § 119(e) or § 120 Benefit

Applicant is advised that the first sentence(s) of the specification following the title should be updated to reflect the status (e.g., abandoned or patented) of all applications relied upon under 35 U.S.C. § 120, 121 or 365(c). Appropriate amendments should be performed.

Perusal of prior applications 10/456,865, filed 06 June, 2003, and 09/636,057, filed 08 August, 2000, failed to provide support for the currently claimed invention. Accordingly, for the purposes of applying prior art under 35 U.S.C. § 102 or § 103, the effective filing date will be that of provisional application no. 60/649,021, filed 31 January, 2005.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 1, 3, 5, 8, and 9 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed toward a "Tat-based tolerogen" comprising a monoclonal antibody (Mab) coupled to an HIV Tat protein. These compositions are purportedly useful for the treatment of autoimmune disorders.

The legal considerations that govern enablement determinations pertaining to undue experimentation have been clearly set forth. *Enzo Biochem, Inc.*, 52 U.S.P.Q.2d 1129 (C.A.F.C. 1999). *In re Wands*, 8 U.S.P.Q.2d 1400 (C.A.F.C. 1988). *Ex parte Forman* 230 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986). The courts concluded that several factual inquiries should be considered when making such assessments including the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of

the claims. *In re Rainer*, 52 C.C.P.A. 1593, 347 F.2d 574, 146 U.S.P.Q. 218 (1965). The disclosure fails to provide adequate guidance pertaining to a number of these considerations as follows:

1) The disclosure fails to provide adequate guidance pertaining to the identification, characterization, and functional properties of any given monoclonal antibody. In order to prepare and employ the claimed compositions, the skilled artisan would require, *inter alia*, a knowledge of the antibody binding specificity, affinity, avidity, and other functional properties. However, the disclosure fails to provide any guidance pertaining to this topic.

2) The disclosure fails to provide any guidance identifying suitable targets that play a role in autoimmunity. In order to practice the claimed invention, the skilled artisan would require a knowledge of the antibody target (i.e., cell type, antigen of interest, cellular location, etc.). However, once again the disclosure fails to provide sufficient guidance pertaining to these parameters.

3) The state-of-the-art as it pertains to the treatment of autoimmune disorders is one of unpredictability (Martin *et al.*, 2001; Hirano, 2002; Waldmann, 2003; Bettelli *et al.*, 2007). To date few immunotherapeutics have been successful at treating autoimmune disorders. This is not surprising considering the complex aetiologies/pathologies associated with these diseases. Factors contributing to the difficulty associated with developing effective immunotherapeutics includes the complex pathology of many immune disorders, the lack of suitable animal models that accurately predict clinical efficacy, and the

inability to target immunotherapeutics to the tissue of interest.

4) The claims are of considerable breadth and encompass any putative therapeutic. However, as discussed above, the specification clearly fails to enable the full breadth of the claimed invention.

5) The disclosure fails to provide any working embodiments. Considering the difficulty associated with developing immunotherapeutics to treat autoimmune disorders, clearly a reasonable number of working embodiments would be required to enable the claimed invention. However, the specification is also silent concerning this concern.

Accordingly, when all the aforementioned factors are considered in toto, it would clearly require undue experimentation from the skilled artisan to practice the claimed invention.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1

Application No.: 10/598,976

Docket No.: 51311-00001

Applicant: Cohen, D. I.

Filing Date: 09/15/2006

(e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

/Jeffrey S. Parkin, Ph.D./
Primary Examiner, Art Unit 1648

06 September, 2008